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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/619,794	07/15/2003	Ian L. Brown	28053/37955A	7883

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EXAMINER

MAIER, LEIGH C

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 11/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/619,794

Applicant(s)

BROWN ET AL.

Examiner

Leigh C. Maier

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13, 15-25, 36 and 37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13, 15-25, 36 and 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 28, 2006 has been entered.

Claim 13 has been amended. Claim 14 has been canceled. Claims 13, 15-24, 36 and 37 are pending. Any rejection or objection not expressly repeated has been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 13-25, 36, and 37 are again rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, as set forth in the previous Office action.

Applicant's arguments filed August 28, 2006 have been fully considered but they are not persuasive. In response to this rejection, Applicant has submitted a declaration under 37 CFR 1.132 is insufficient to overcome the rejection of claims as set forth in the last Office action because the reference cited in the specification (Brown) in turn cites Prosky, and these citations would direct one of ordinary skill to the method of measurement (AOAC Method 985.29).

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However, the reference is cited in the specification with respect to the definition of “resistant starch” not the method of measuring said starch. As discussed previously, there are several methods known in the art, and if there are several different ways of calculating a parameter, and the specification fails to indicate which method is to be employed, then the claims are indefinite, *Harrah's Entertainment Inc. v. Station Casinos Inc.*, 71 USPQ2d 1439 (DC Nev 2004).

Claim Rejections - 35 USC § 102

Claims 13, 15-20, 36 and 37 are again rejected under 35 U.S.C. 102(b) as being anticipated by WIBERT et al (US 5,776,887) with SEIB (US 5,855,946) and SAJILATA et al (Comp. Rev. Food Sci. Food Safety, 2006) for inherency.

WIBERT discloses a drink comprising 3.3 g of a vegetable oil blend and 6.667 g of Novelose® a starch comprising 33% RS. (See SEIB at Table V.) This composition comprises RS in a proportion of about 22% by weight of the total carbohydrate content. Regarding claim 15, the references do not disclose the percentage of amylose in the Novelose® starch used. However, the percentage of RS is not necessarily the same as the percentage of amylose. For example, see Sajilata at page 6, second column “Amylose:amylopectin ratio.” The reference states that “the meals containing high amylose (70%) corn flour had an RS of 20 /100 g DM than that containing ordinary corn flour (25% amylose) that had RS of 3 g/100 g DM.” Therefore, it would be expected that the Novelose® product would have greater than 50% amylose. Since the Office does not have the facilities for preparing the claimed materials and comparing them with prior art inventions, the burden is on Applicant to show a novel or unobvious difference between the

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claimed product and the product of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

Applicant's arguments filed August 28, 2006 have been fully considered but they are not persuasive.

Applicant contends that Wibert sets forth "a laundry list of vegetable and non-vegetable fats ... including many that are primarily saturated including coconut oil, palm kernel oil, milk fat, and egg yolk lipid." The examiner agrees that some (but not a majority – five out of twelve by the examiner's count) of the oils listed are primarily saturated. However, if one were to limit the list to "vegetable oils," the type of fat used in the cited example, the list comprises six primarily unsaturated and three primarily saturated ones. Furthermore, it is noteworthy that most of the examples list "vegetable oil" as the fat component, but two examples, 6 and 7, specifically list "modified palm/palm kernel oil," apparently differentiating that particular fat from "vegetable oil." Therefore, it appears more likely than not that what is used is one of the oils that one more typically associates with the term "vegetable oil," such as corn or soybean, primarily unsaturated fats.

Claim Rejections - 35 USC § 103

Claims 13, 15-23, 36, and 37 are again rejected under 35 U.S.C. 103(a) as being unpatentable over WIBERT et al (US 5,776,887) with SEIB (US 5,855,946) and SAJILATA et al.(Comp. Rev. Food Sci. Food Safety, 2006) for inherency as above.

WIBERT teaches as set forth above. The reference does not exemplify a composition having an energy content as recited in claims 21-23. However, the reference specifically suggests

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the preparation of compositions that are “nutritionally complete” so that the composition contains adequate nutrients, including calorie levels that provide energy, to sustain healthy human life for extended periods. The reference further suggests the use of the composition for enteral feeding. In such a situation, one of ordinary skill would understand that the composition would provide most, or more likely all, of a patient’s nutrition. Begin col 5, line 65, continuing through col 6, line 17.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to prepare compositions having adequate energy for part of or all of a patient’s needs, as expressly suggested by the reference. One of ordinary skill would reasonably expect success in preparing such compositions. Furthermore, with respect to the type of fat used, in preparing a bulk composition, for example what would be needed for providing nourishment to a patient for an extended period of time, the use of a primarily saturated fat, such as palm oil, would still result in a composition having at least 2g of unsaturated fat.

Applicant’s objection to the types of oils described by Wibert has been addressed above.

Applicant further contends that only one of Wibert’s eight examples disclose a proportion of RS to carbohydrate greater than 20%. First of all, it would be obvious to one of ordinary skill to use and modify (within the teachings of the reference) *any* of these examples. Because it happens to be one of eight does not make it less obvious. In the absence of unexpected results, it would be within the scope of one of ordinary skill to modify any of the examples within the scope of the teachings of the reference. Applicant has not demonstrated any particular criticality in the use of this ratio.

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Applicant argues that the rejection stating that “those of ordinary skill in the art would have modified the disclosure of Wibert to ‘attain adequate energy requirements’ so as to fall within the scope of the claims is inappropriate in the absence of some concrete teaching that the reference be so modified. The Wibert reference teaches what it teaches.” The examiner agrees, and what the reference expressly teaches is the preparation of the composition in an amount to provide a full day’s nutrition for a patient. See col 4, lines 45-60. It would certainly be within the scope of the ordinarily skilled practitioner to determine the appropriate calorie level for a diabetic patient. Applicant has demonstrated no criticality in any particular calorie range.

Claims 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over WIBERT et al (US 5,776,887) with SEIB (US 5,855,946) for inherency as above, as applied to claims 13, 15-23, 36, and 37 and further in view of KLOR et al (US 5,886,037).

WIBERT teaches as set forth above. The reference does not teach the composition as a powder or granule.

KLOR teaches a reconstitutable powder composition comprising 46 wt% carbohydrate, 20 wt% protein and 29.6 wt% fat. The fat component is a particular combination of fats, but consistent with the suggested fats of WIBERT. See the example and col 4, lines 56-63. The carbohydrates suggested in KLOR are consistent with those used in WIBERT. Furthermore, they both have the same intended use, i. e. oral or tube feeding of diabetics.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to prepare the WIBERT composition in the form of a reconstitutable powder. One of ordinary skill would be motivated to prepare the composition in such a form for

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convenience (less weight) in shipping and convenience (greater portability) for the consumer.

The artisan would reasonably expect success in preparing the composition in such a form, because KLOR had taught that a similar composition could be prepared in such a manner. Even if one were to combine the references in such a way that used the KLOR fat formula (at least 45% saturated fat), the preparation of the composition in a bulk amount, which would be obvious from the references, would result in a composition having at least 2g of unsaturated fat.

Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Thursday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Anna Jiang (571) 272-0627, may be contacted. The fax number for Group 1600, Art Unit 1623 is (571) 273-8300.

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Leigh C. Maier

Leigh C. Maier
Primary Examiner
November 8, 2006